

JAN 5 2006

K 053209

SunTech Medical Inc.
510(k) Submission
Tango + System for
Non-Invasive Blood Pressure and Per Cent
Oxygen Saturation

510(K) Summary
June 22, 2005

(1) Submitter information

Name : SunTech Medical Inc.

Address: 507 Airport Boulevard
Morrisville, NC 27560

Telephone: 1 919 654-2300

Contact person: David Gallick (Official Correspondent).
SunTech Medical Inc.
507 Airport Boulevard
Morrisville, NC 27560
1 919 654 2332

Date prepared : June 22, 2005

(2) Name of Device

Trade Name: Tango+ Automatic Blood Pressure and Oxygen Saturation Measurement System

Common Name: Automated Blood Pressure Monitor and Oxygen Saturation measurement device

Classification name: System, measurement, blood pressure, non-invasive, systolic and/or diastolic, 74JOE, 870.1130

(3) Legally-marketed predicate devices

SunTech Tango, K970629

Nonin Avant 2120, K031487

page 1 of 2

(3) Description

The Tango+, a microprocessor based ambulatory blood pressure monitor and oxygen saturation measurement system intended to be used with stress-test systems, uses Korotkoff sounds to determine blood pressure and an optical finger sensor for oxygen saturation. An internal electric pump is used to inflate the cuff, and deflation is controlled by two valves. Tango+ has the ability to make blood pressure at predetermined intervals (normally from a schedule determined by the physician), or on demand. Saturation measurements are updated once per second.

(4) Intended Use

The Tango+ is intended to be used as an adjunct to exercise stress testing devices. It is intended to measure and display diastolic and systolic blood pressure, heart rate, and percentage of oxygen saturation in arterial blood (SpO₂) in adult patients during stress tests.

(5) Performance Data**(a) Non-clinical tests**

The Tango+ will have passed the following tests:

- EN 60601-1 for Electrical Safety
- EN 60601-1-2 for Electromagnetic Compatibility
ANSI/AAMI SP10

The oxygen saturation system has been thoroughly tested.

The components have had biocompatibility tests.

(b) Clinical tests

The SpO₂ system was validated in a clinical test.

(6) Conclusion

The Tango+ Automated Blood Pressure and Oxygen Saturation Monitor system is equivalent in safety and efficacy to the legally-marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 5 2006

SunTech Medical, Inc.
c/o Mr. David Gallick
VP of Engineering
507 Airport Boulevard
Morrisville, NC 27560

Re: K053209

Trade Name: Tango+ Automatic Blood Pressure and Oxygen Saturation Measurement
System

Regulation Number: 21 CFR 870.1130

Regulation Name: Non-Invasive Blood Pressure Measurement System

Regulatory Class: Class II (two)

Product Code: DXN

Dated: November 09, 2005

Received: November 16, 2005

Dear Mr. Gallick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

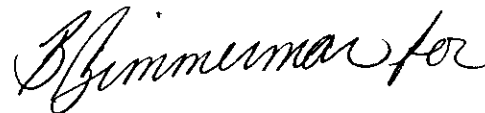
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. David Gallick

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

K053209**Indications for Use Form****Device Name:** Tango+**Indications for Use:**

The SunTech Medical Tango+ Pulse Oximeter and NIBP monitor is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate, and blood pressure of adult patients in hospitals, medical facilities, and subacute environments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. Zimmerman
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053209